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Recommended Citation

Peter L. Strauss, *Geier v. American Honda Motor Co.: A Story of Statutes, Regulation and the Common Law*, COLUMBIA PUBLIC LAW RESEARCH PAPER NO. 09-223 (2009).

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Columbia Law School

Public Law & Legal Theory Working Paper Group

Paper Number 09-223

GEIER V. AMERICAN HONDA MOTOR CO.: A STORY OF STATUTES, REGULATION AND THE COMMON LAW

(version of Oct. 10, 2009)

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Geier v. American Honda Motor Co.: A Story of Statutes, Regulation, and the Common Law

Peter L. Strauss¹

Executive Summary: This story tells the tale of a lawsuit brought on behalf of a teenager whose injuries from an accident might have been lessened if her car had contained an airbag. Plaintiffs sued on the straightforward basis that the design choice to omit a safety device of proven merit made the car unreasonably hazardous. Federal safety regulations had required the maker of her car to install some such device as an airbag in at least 10% of the cars it made the year it made her car – but her car had only a manual lap-and-shoulder belt (which she had used). Just weeks before her accident, Congress had passed a statute requiring airbags in ALL cars – but not for several model years into the future. Whether federal law allowed the case to proceed proved to be a matter as complex as its theory of liability was simple. At issue was a statute that in one section gave the federal government exclusive authority to set auto safety standards and in provided for the saving of common law claims. How did these two provisions interact? The following story shows just how complicated the question was by looking at the history of both design defect liability (still nascent at the time Congress passed the legislation in question) and federal standards on airbags (finally promulgated only after more than a decade of wrangling). Unsurprisingly, this background produced a variety of perspectives—and outcomes—in state and federal cases prior to the suit at issue here. Introducing even further difficulties was a contemporaneous set of Janus-faced Supreme Court decisions on federal pre-emption of state tort law. Only after taking all of these considerations into account does this story examine the litigation choices of plaintiffs’ and defense counsel in the suit in question, as well as the opinions in the Supreme Court. Drawing on two very recent Supreme Court decisions invoking the relationship between regulatory and judge-made law, the essay invites the reader to view the case less in terms of conflict between federal prerogatives and state sovereignty, and more as involving the accommodation of the competing modes of lawmaking and the influence of time’s passage in the modern state.

Geier v. American Honda Motor Co.,² the subject of this story, provides a good context in which to consider a welter of issues: the implications for common law development of an age of statutes and regulation, the impacts of common law development on statutory meaning, the arguable importance to statutory interpretation of legal understandings prevalent when a statute is

¹ Betts Professor of Law, Columbia University. Many thanks to Andrew Amend, CLS '08, for able research and editorial assistance.

² 529 U.S. 861 (2000).

enacted, the relevance to pre-emption questions (if any) of congressional equivocation about the implementation of arguably pre-emptive federal programs, and other contemporary disputes about pre-emption of state law by federal.

In considering this story, keep in mind the changes the centuries have wrought. When questions of pre-emption first arose, statutes were relatively rare and law-making regulators rarer; federal law-making authority was thought much more limited than it is today; and most state law emanated from the mouths of judges, through the common law. Consequently, early statements about pre-emption naturally supposed (“presumed”) a relatively limited impact of federal law on state law-making in the traditional areas of law reserved to state authority—that is to say, the arena of everyday common law. Today, statutory and regulatory law have displaced the common law (that is, judge-made law) as the chief sources of legal development: we consider the law judges “find” or make as subordinate to the law adopted by the politically responsible actors who make up our legislatures and executive agencies. Yet this story presents a federal statute that explicitly denied state legislatures and executives authority to vary federal regulations, while paradoxically appearing to preserve that possibility for common law judges. It is no surprise that the opinions in this case, like those in pre-emption cases generally, are laden with appeals to—and disagreement about—the “federalism” values that today lead many to question national authorities’ incursions on state initiatives. Less obvious is that these cases may also implicate the allocation of responsibility among legislative, executive (regulatory) and judicial authority. In an era when judges’ common-law lawmaking is clearly secondary to other sources of law, are there reasons to distinguish among state legislative, executive and judicial actors in thinking about pre-emption issues?

Background: Factual, Regulatory, Judicial

Alexis Geier's Accident and Federal Regulation of Airbags

At 10:30 one January night in 1992, seventeen-year-old Alexis Geier was driving down MacArthur Boulevard, a divided roadway in Washington, D.C. that curves gently before its 4900 block. It was half an hour before the beginning of the curfew Washington law imposes on licensed drivers younger than eighteen. For reasons the record does not reveal,³ she lost control of the 1987 Honda Accord she was driving and crashed into a tree. She was wearing a seat belt at the time, but the force of the crash is said to have broken the back of her seat and to have dislodged the seat from its track. The Accord had no airbag. Her collisions with the inside of her car caused severe injuries that an airbag might have lessened or even prevented. In conformity with a federal regulation requiring 10% of all passenger vehicles manufactured that year to contain passive restraint systems,⁴ such as airbags or automatic seat belts, other Hondas from the 1987 model year had passive restraints installed. But while the regulation gave automobile manufacturers extra credit toward that threshold for choosing the more expensive airbag option, its only *universal* restraint requirement was for the familiar manual lap and shoulder safety belts Ms. Geier was using. Airbags would not be required of *all* passenger cars until the 1998 model year, under a statute Congress had enacted four weeks before her accident.⁵

³ Ice on the road was certainly a possibility, but readily available records do not reveal the temperature or whether it had recently been raining on the day of the accident, January 12; Washington received only a trace amount of snow during that month. <http://www.erh.noaa.gov/lwx/climate/dca/dcasnow.txt> (visited June 15, 2009).

⁴ A passive restraint, such as an airbag or an automatic seatbelt, operates without the need for the person protected to do anything, such as to buckle up.

⁵ On December 18, 1991, Congress enacted the Intermodal Surface Transportation Efficiency Act of 1991, Pub. L.

Airbag technology had already been available for more than twenty years. The National Highway Traffic and Safety Administration [NHTSA], a federal agency within the national Department of Transportation, had adopted the first regulation requiring the use of passive restraints, including airbags, in 1972.⁶ The National Traffic and Motor Vehicle Safety Act of 1966 [Safety Act] had charged the Department with developing safety standards for American automobiles that would be “practicable,” would “meet the need for motor vehicle safety,” and would apply throughout the country.⁷ Among the Department’s initial efforts was a 1967 regulation, Federal Motor Vehicle Safety Standard 208, requiring manual safety belts in all cars.⁸ NHTSA’s departmental predecessor started considering a requirement of passive restraints such as airbags in 1969. Passive restraints, it was hoped, would protect the many drivers and passengers who were failing to buckle up. (The usage rate for voluntary restraints reported in NHTSA’s explanation of the rule at issue in *Geier* was 12.5%.) The revisions of Standard 208 that NHTSA adopted in 1972 would have required installation of passive restraints (airbags or automatic seat belts) in all automobiles manufactured after August 15, 1975. On review of this rule, the Court of Appeals for the Sixth Circuit (sitting in the automobile capital, Detroit) accepted the safety advantages of airbags. But it found that the neck of the dummy used to test their compliance with the rule was too stiff in relation to human necks; for this reason alone, it vacated the standard’s passive restraint requirements and sent them back to the agency for further

No. 102-240, directing NHTSA to amend Standard 208 to require airbags in 95% of 1997-model automobiles and 100% of 1998-model automobiles. Standard 208, as revised by Secretary Dole, had by this time taken full effect.

⁶ 37 Fed. Reg. 3911 (1972). Those who are interested can find a good deal about this agency’s current activities, including its continuing involvement with airbag issues, at www.nhtsa.dot.gov.

⁷ 15 U.S.C. § 1392(a) (now 49 U.S.C. § 30111(a)).

⁸ Federal Motor Vehicle Safety Standard 208, 32 Fed. Reg. 2415 (1967).

consideration.⁹ Left in place was an annoying ignition interlock feature, that required the driver and any front seat passenger to attach their seat belts in order to start the car. Public fury over the inconveniences of this device spawned legislative amendments in 1974 that, together with administrative actions over the ensuing decades, postponed again and again the actual introduction of a feature that might annually have saved 12,000 lives and prevented over 100,000 serious injuries.¹⁰ When, less than a month before Ms. Geier had her accident, Congress at last provided that airbags must be universally installed, it was not in time to prevent her grievous injuries.

Congress had passed the Safety Act in 1966 against a backdrop of increasing concern about the safety of American automobiles, and in particular the “second collision” in any accident—that between a driver or passenger and the inside of her car. A year earlier, Ralph Nader had burst onto the scene with two books, *Unsafe at Any Speed: The Designed-In Dangers of the American Automobile* and *Automobile Design Hazards*, that would rival Rachel Carson’s environmentalist classic *Silent Spring* (1962) in their impact on American consciousness. The common law was not dealing with these issues, although one might have thought change loomed. In 1965, after much debate, the American Law Institute had adopted section 402A for its Second Restatement of Torts, “Special Liability of Seller of Product for Physical Harm to User or

⁹ Chrysler Corp. v. Department of Transportation, 472 F.2d 659, 675 (6th Cir. 1972).

¹⁰ Motor Vehicle and School Bus Safety Amendments of 1974, Pub. L. 93-492, § 109, 88 Stat. 1482, 15 U. S. C. § 1410b(b). In addition to abolishing the “interlock” standard, Congress prohibited NHTSA from issuing any standard requiring airbags or any other non-belt restraint system unless the standard was submitted first to both houses of Congress and not disapproved by them. 15 U.S.C. § 1410(b), (c). The whole story is elegantly told, through the ‘80’s, in Jerry Mashaw and David Harfst, *The Struggle for Auto Safety* (1990). The accounts in pages following often draw on their detailed and insightful history.

Consumer.” A statement of strict liability principles, its general language¹¹ could be understood to reach what are today the well-established common law causes of action for design defect and failure of proper warning. Yet, as Yale Law School Professor George Priest abundantly showed a quarter century later,¹² its drafters had never imagined that the words of section 402A encompassed these causes of action; the American Law Institute’s debates and its Reporters’ examples imagined only the “manufacturing defect” cases that had by that time become common occasions for imposing “strict liability” throughout American law. No car manufacturer had yet been found liable for either design defects or failures to warn, albeit the “breach of warranty” claims for manufacturing defects that Restatement 402A now recharacterized as a strict liability tort were commonplace. Today, “design defect” and “failure to warn” are separately and explicitly addressed in the Third Restatement of Torts; but in 1965 they were only beginning to take shape.¹³

¹¹ “§ 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer.

“(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

“(a) the seller is engaged in the business of selling such a product, and

“(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

“(2) The rule stated in Subsection (1) applies although

“(a) the seller has exercised all possible care in the preparation and sale of his products, and

“(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.”

¹² George Priest, *Strict Products Liability: The Original Intent*, 10 Cardozo L. Rev. 2301 (1989).

¹³ Notably, the Third Restatement’s provisions, ALI, *Liability of Commercial Product Sellers Based on Product Defects at the Time of Sale* § 2 (1998), treat only manufacturing defect liability as strict, in the sense that it is available “even though all possible care was exercised”; liability for defective design or failure to warn depends on the familiar negligence ideas of foreseeability of harm and (un)reasonableness of behavior given its possibility. In

It was against this backdrop of public alarm and common-law ineffectiveness that Congress enacted the Safety Act in 1966, creating a federal agency with responsibility for developing standards (regulations) to improve automotive safety. The Safety Act contained two provisions whose eventual tension the Supreme Court would not attempt to resolve for more than three decades, in *Geier*. One provision explicitly addressed the question of state authority to adopt motor vehicle standards varying from any that NHTSA might adopt. Section 1392(d) of Title 15 (now 49 U.S.C. § 30103(b)) provided:

“Supremacy of Federal standards; allowable higher standards for vehicles used by Federal or state governments. Whenever a Federal motor vehicle safety standard established under the subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment, any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to a Federal safety standard. Nothing in this section shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a safety requirement applicable to motor vehicles or motor vehicle equipment procured for its own use if such requirement imposes a higher standard of performance than that required to comply with the otherwise applicable Federal standard.”

The second provision was a savings clause for common law actions. Section 1397(k) of Title 15 (now 49 U.S.C. § 30103(e)) provided:

“Continuation of common law liability. Compliance with any federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”¹⁴

Perhaps you immediately see the tension between these two provisions, given the present state of common law liability for design defects and failures to warn. While reserving the right of states

applying the “all possible care” language of Restatement Second § 402A to manufacturing defects only, the Third Restatement in effect ratifies Professor Priest’s account.

¹⁴ 15 U.S.C. § 1397(k) (currently codified at 49 U.S.C. § 30103(e)).

to contract for greater safety than federal standards provide in cars bought for their own use, Section 1392(d) is explicit that state legislatures and state administrative agencies can enforce no legal obligation inconsistent with a federal regulatory standard. Yet if section 1397(k) encompasses common law liability for design defects, it might seem in effect to permit state judges and juries to do just that: it would grant them authority to say that a car designed in compliance with federal standards has been defectively designed if compliance with those standards nonetheless fails to make it “reasonably safe”—fails to meet the common law standard of reasonable design to reduce or avoid foreseeable risks.

Fast forward now to 1992, and consider the circumstances facing the attorneys the Geiers and their daughter consulted in the wake of her accident. The safety benefits of airbags and the feasibility of their technology had been established for two decades. Whatever the understanding of section 402A by the ALI and its reporters in the 1960s, by 1992 courts had found in it an endorsement of strict liability for both design defects and failures to warn.¹⁵ Just weeks before the accident, Congress had (finally!) awakened to the need to see airbags installed in every car. True, the legislative judgment embodied in that new statute would not be fully effective as a statutory requirement until the 1998 model year, but it dramatically confirmed what everyone now knew reasonable safety required. In the face of what automobile companies had known and been able to do for decades, irrespective of federal requirements, might one not convince a judge or a jury that a car without airbags had not been safely designed? This was the theory on which the Geiers’ attorneys sued, seeking \$10,000,000 compensatory damages, and \$10,000,000 punitive damages for Alexis, and an additional \$500,000 to compensate her parents for the harms

¹⁵ Priest, *supra* note 12. The Third Restatement was to recharacterize these causes of action in terms of “reasonable” behavior, restoring a negligence flavor to them.

they said they had suffered in looking after her for the half-year between her accident and her eighteenth birthday, when she reached majority.

The Geiers were not the first to make such arguments, and the legal landscape was a complex one. Congress's action in 1974¹⁶ had placed an unusual hurdle in the path of requiring passive restraint systems like airbags in American cars—a tribute, perhaps, to each American's desire for freedom to decide for herself just how much risk she wished to take in driving. The move also may have reflected resistance to airbags' expense and fears that they might deploy unnecessarily, or even prove unsafe for some (smaller) passengers in a crash. Aware of the public's resistance, President Ford's Secretary of Transportation, William Coleman, had then issued an amendment to Standard 208 that envisioned equipping only 500,000 cars with airbags. The (voluntary) purchasers of these vehicles would in effect be participants in a "demonstration project" that might serve to convince the public of their worth.¹⁷ But his amendment would not take effect until the presidency of Jimmy Carter (1977-81). President Carter's Secretary of Transportation, Brock Adams, was thoroughly convinced of the safety benefits of passive restraint systems, and so withdrew Secretary Coleman's regulation and substituted one *requiring* passive restraint systems in all cars in future model years. Now, however, the first such year fell in the administration of Ronald Reagan (1981-89).¹⁸ Apparently carrying out President Reagan's

¹⁶ See *supra* note 10 and accompanying text.

¹⁷ Department of Transportation, The Secretary's Decision Concerning Motor Vehicle Occupant Crash Protection (Dec. 6, 1976), App. 2068.

¹⁸ 42 Fed. Reg. 34289 (1977). The modified standard left automobile manufacturers free to choose between airbags and passive belts, and survived both judicial, *Pacific Legal Foundation v. Department of Transportation*, 593 F.2d 1338 (D.C. Cir. 1979) and congressional scrutiny. Nonetheless, congressional resistance to a mandatory airbag requirement appeared from time to time; as the Supreme Court would later report, "an overwhelming majority of the Members of the House of Representatives voted in favor of a proposal to bar NHTSA from spending funds to administer an occupant restraint standard unless the standard permitted the purchaser of the vehicle to select manual rather than passive restraints. 125 Cong. Rec. 36926 (1979)." Motor Vehicles Manufacturers Association of the

campaign pledge to lift economic and regulatory burdens from the American automobile industry, *his* Secretary of Transportation, Andrew Lewis, suspended and then rescinded this requirement. NHTSA's explanation of this change reported that manufacturers intended to meet the passive restraint requirement by installing their cheapest manufacturing option, "automatic" seat belts *that could be detached*, in 99% of their cars. But, NHTSA reasoned, these were little better than manual seat belts; they could be left detached, and virtually everyone who was not yet using seat belts would treat them that way. For this reason, the added expense of providing them had no justifying safety benefit, and the public would see them as yet another intrusion of the "nanny state," further poisoning attitudes toward safety regulation.

After the Supreme Court invalidated NHTSA's action for reasons usually considered in courses on Administrative Law,¹⁹ Secretary Lewis's successor in the Reagan Administration, Elisabeth Dole, promulgated the version of Standard 208 in effect at the moment of Alexis Geier's accident.²⁰ Subject to an unrealized contingency (that by April of 1989 two-thirds of the states would have enacted laws requiring use of manual seat belts and meeting certain other criteria),²¹ the revised standard provided that passive restraints would eventually be required in all passenger cars. In the interim, it created an immediately effective schedule requiring a minimum of 10% of the 1987 model year cars manufactured after September 1, 1986 to use some type of automatic protection, but not necessarily airbags. The figure would increase to twenty-

United States v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 46 n.10 (1983).

¹⁹ *Motor Vehicles Manufacturers Association*, 463 U.S. 29.

²⁰ 49 Fed. Reg. 28962 (July 17, 1984).

²¹ "Click it or ticket" laws became commonplace, but many, apparently with the understanding that the federal standard would therefore take effect, did not satisfy the other criteria.

five percent of the 1988 model year cars, and forty percent of the 1989 model year cars. According to the standard's statement of basis and purpose,²² the phase-in was necessary because of "the need for the public to become accustomed to the technology and the need for protection, and [because] an across-the-board mandate too quickly could engender adverse public reaction."²³ The standard gave manufacturers an incentive to choose the more expensive airbag (or other as-yet unproven passive interior techniques) over passive seatbelts: for every two cars in which the manufacturer *did* install an airbag or qualifying passive interior, it would be credited with three cars towards its annual quota. "By starting off with a relatively small percentage and building up to full compliance, the phase-in will provide the manufacturers with a better opportunity to manage unforeseen development and production problems and, as a result, also make it less likely that consumers will develop adverse impressions based upon earlier experience."²⁴ In the margin, there is a longer excerpt from this part of a statement of basis and purpose that ran dozens of pages in the Federal Register (the rule itself took only about a page of print).²⁵ In it, one finds an italicized phrase suggesting that potential liability would help

²² The procedures required to adopt regulations like Standard 208 form an important component of courses in Administrative Law. Here it may be sufficient to say that the federal Administrative Procedure Act, 5 U.S.C. § 553, ordinarily requires three elements: published notice of a proposal; a subsequent opportunity for any interested member of the public to comment on the proposal; and, on adoption, an accompanying statement of basis and purpose. While the statute calls for these statements to be "concise" and "general," agency practice for any rules of importance (encouraged by years of judicial oversight) is to make them quite extensive. They set the framework within which judicial review occurs. The Department of Transportation's website gives a useful introduction to rulemaking procedures generally at <http://regs.dot.gov>.

²³ 49 Fed. Reg. at 28989.

²⁴ *Id.* at 29000.

²⁵ *Id.* at 28999-29000:

"The Phase-In . . .

"The Department decided to phase in the requirement for automatic occupant crash protection for a number of reasons.

motivate manufacturer behavior. Geier's attorneys would make that six-word phrase into the focus of their oral argument, construing it as the Secretary's concession that design defect liability might lie.

"First, by phasing-in, some automatic protection systems will be available earlier than if implementation were delayed until the systems could be installed in all automobiles. The earliest the Department could have required automatic protection in 100 percent of the fleet would have been September 1, 1987. . . . If the Department had required full compliance by September 1, 1987, it is very likely all of the manufacturers would have had to comply through the use of automatic belts. Thus, by phasing-in the requirement, the Department makes it easier for manufacturers to use other, perhaps better, systems such as airbags and passive interiors. . . .

"The specific percentages used for the phase-in were chosen because they balance technological feasibility with the need to encourage technological innovation. These percentages should also provide the gradual phase-in that the Department believes will help build up public acceptance. [Then some passages on enforcement of the percentage requirements.] . . .

"Thus, the use of a phase-in appropriately takes into account the abilities of the different manufacturers to comply with the requirement, encourages the use of different, and perhaps better, means of compliance, and provides the public with an opportunity to better understand the value of automatic protection. The phase-in will permit the manufacturers to ensure that whatever system they use is effective, trouble-free, and reliable. By starting off with a relatively small percentage and building up to full compliance, the phase-in will provide the manufacturers with a better opportunity to manage unforeseen development and production problems and, as a result, also make it less likely that consumers will develop adverse impressions based upon earlier experience.

"Some commenters suggested that the manufacturers would use the cheapest system to comply with an automatic restraint requirement under our [Mandatory Use Law] alternatives. They said the short time allowed for passage of MULs would force the manufacturers to choose the least expensive alternative so that they would lose little in investments if sufficient numbers of MULs passed. The Department does not agree with this contention. It believes that competition, *potential liability for any deficient systems* and pride in one's product would prevent this. The phase-in schedule should provide adequate time to design and produce high quality systems.

"The Credit for Nonbelt Restraints

"The rule also permits manufacturers to receive extra credit during the phase-in period if they use something other than an automatic belt to provide the automatic protection to the driver. . . . As a result of this option, manufacturers will be able to get extra credit for the use of airbags, passive interiors, or other systems that meet the test requirements of the rule.

"There are a number of reasons for the Department's decision to permit this option. First, it believes that the primary system that would be used under this 'extra credit' alternative would be the airbag. As the data in Table 5 clearly illustrate, airbags should provide very significant safety benefits. Even though fewer cars would be equipped with automatic protection if extra credit is given for airbag automobiles, airbags—when used with belts—are very effective. In addition, the Department believes that there is a definite advantage in the initial stages of compliance with this rule to encourage the use of various automatic protection technologies. This should promote the development of what may be better alternatives to automatic belts than would otherwise be developed. If enough alternative devices are installed in automobiles during the phase-in period, it will also enable the Department to develop a sufficient data base to compare the various alternatives to determine whether any future modifications to the rule to make it more effective are necessary or appropriate."

How did the new rule interact with sections 1392(d) and 1397(k)? Clearly enough, the Geier’s attorneys would have reasoned, section 1392(d) prevented any state—including, for these purposes, the District of Columbia²⁶—from adopting certain types of regulation. No administrative rule it might adopt could force the choice of airbags over automatic seatbelts, create a greater regulatory incentive to make that choice, or require passive restraints of *any* character on more than 10% of 1987 model year cars. Moreover, since Ms. Geier had been wearing her manual lap and shoulder belt, it would have been hard to claim she would have suffered less damage had an automatic seatbelt been installed.²⁷ Did section 1397(k) open the door for the courts to find both liability grounded in a design defect, and that design defect standards could be met only by airbags?.

Design Defect Cases in the State and Lower Federal Courts

The landscape of judicial decision was complex as well. Before delving into these cases, it may be helpful to provide a brief glossary of terms courts employ in deciding whether state law has been preempted, both in general and in the specific context of products liability actions.

Affirmative Defense: The chapter of the Third Restatement of Torts concerned with commercial sellers’ liability for product defects provides in section 4(b) that “a product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the

²⁶ 45 U.S.C. § 1391(8), recodified as 49 U.S.C. § 30102(10). Of course, the District of Columbia is *not* a state, and its law is subject to congressional control to a degree not experienced in New York or Arizona. Every reader may be bemused, and D.C. residents gratified, by the unselfconscious invocation of federalism concerns in the *Geier* opinions.

²⁷ Indeed,, she might have suffered more. See *Montag v. Honda Motor Co.*, 75 F.3d 1414 (10th Cir. 1996) (design defect liability rejected where a federal-standard-compliant automatic seat belt disengaged, as it was designed to do, when the driver’s side car door opened under a *side* impact with a freight train at a railroad crossing, ejecting the driver from the car).

risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.”²⁸ If a federal standard does not pre-empt a state tort action, as when it provides only a minimum floor required for safety and does not purport to be exclusive, compliance with that standard is thus a necessary but not a sufficient condition to establish an affirmative defense to the complaint.

Express Pre-emption: A federal statute or agency regulation may in terms describe state law that is or is not permitted to co-exist with it. The Supremacy Clause of the U.S. Constitution makes these declarations controlling. Whether such declarations, when made, are then to be regarded as the *exclusive* source of pre-emption, and with how much respect for residual state authority in areas (like torts) of traditional state responsibility they are to be interpreted, are among the questions to keep your eye on.

Implied Pre-emption: Whether or not a statute or regulation provides for express pre-emption, pre-emption might be thought implicit in several situations:

Field Occupation: The nature of a federal program makes clear that it occupies the field, leaving no room for competing, conflicting state law.

Impossibility: A state standard is such that a federal standard cannot be complied with without violating it—as, for example, if a federal standard absolutely required the installation of airbags in the front passenger seat, and state common law would permit that installation to be regarded as a design defect if a jury found its risk of killing small passengers unreasonable in relation to its safety benefit.

Frustration: Even if the federal standard is complied with, also enforcing a supplementary state standard may frustrate central purposes and objectives of the federal scheme. For example, a federal standard permits automobile manufacturers to choose among different types of protective devices like airbags, and to install them only gradually, over time, in order to win public acceptance of them and permit orderly research and development. The standard leaves any manufacturer free to choose to install airbags in all cars it markets; but a state “design defect” rule making air bags the only choice would frustrate the standards’s objectives. (This is the situation arguably presented in *Geier*.)

With these concepts in mind, let us consider the state of the law in the years just after the ALI had adopted section 402A and Congress had enacted the Safety Act. Courts had begun applying “strict liability” principles to automobiles.²⁹ But these initial cases concerned manufacturing defects, or problems with design that were not reached by a federal standard. It

²⁸ American Law Institute, *Liability of Product Sellers Based on Product Defects at the Time of Sale* § 4(b) (1998).

²⁹ *E.g.*, *Larsen v. General Motors Corp.*, 391 F. 2d 495, 506 (8th Cir. 1968).

took until 1988 for an appellate court to reach the tension created by having a federal standard that explicitly permitted automobile manufacturers to continue selling automobiles that lacked demonstrably effective and feasible safety equipment—that is, automobiles that while meeting relevant federal safety standards state *political* authorities could not vary nonetheless might be found to have “design defects” under the developing common law test. In *Wood v. General Motors Corp.*,³⁰ Chief Judge Levin H. Campbell’s opinion for the majority of a divided First Circuit panel, reporting about two dozen such law suits then pending at the trial level, treated the language of section 1397(k) as Professor Priest had argued Restatement section 402A should have been understood.³¹ It reasoned that, for the Congress of 1966, “the only kind of legal claim which could give rise to the present dilemma—a cause of action based upon alleged automobile design defects—had yet to take its place in the arsenal of the plaintiff’s bar. We infer from this, as well as from the total silence of the legislative record concerning the present dilemma, that Congress simply did not anticipate the situation that now confronts us.”³² The majority thought that “had Congress [foreseen the development of design defect common law] the same logic that dictated . . . Sec. 1392(d) would inescapably have dictated [it] extend to this situation.”³³ Nonetheless, Congress’s failure of anticipation precluded a finding that Congress had *expressly* pre-empted state common law development. Rather, the majority found pre-emption *implied*—leaving open the possibility of suits for defective or defectively designed airbags under the

³⁰ 865 F.2d 395 (1st Cir. 1988), *cert. denied*, 494 U.S. 1065 (1990). Justice Breyer, author of the majority opinion in *Geier*, was sitting on the First Circuit at the time, but was not a member of the panel deciding *Wood*.

³¹ See Priest, *supra* note 12.

³² 865 F.2d at 402.

³³ *Id.*

developing common law.³⁴ A vigorous dissent by Judge Bruce M. Selya argued that the Safety Act was “passed in the midst of . . . turbulent change” in the common law embracing design defects, and that Congress could have been explicit had it wished.³⁵ For Judge Selya, then, the statute’s preservation of “common law” trumped the section title’s characterization of its work as a “continuation” of existing remedies³⁶ Invited by the Supreme Court to express the views of the United States about the petition for certiorari Wood then filed, the Solicitor General supported the result and told the Court no present conflict warranted giving the matter its attention.

Could—should?—the First Circuit have found that section 1397(k) preserved *only* those kinds of common law actions of which the 1966 Congress was clearly aware—actions that sprang from individual failures of product performance and thus did not threaten apparent inconsistency with section 1392(d)? That is, does the “Continuation” of section 1397(k)’s title embrace only the preservation of those causes of action that an informed person would have been certain existed at the moment Congress wrote? Or does the section’s reference to the “common law” carry with it acceptance of the potential for growth and change associated with judge-made law, in the context of a ferment about the deficiencies in automobile safety that reached well past this particular statute? If one is denying the right to take actions inconsistent with federal standards to politically responsible state officials, legislative and executive, why would one choose to permit the courts to take such actions? Or is this perhaps the wrong question, because a given trial verdict on “design defect” does not in itself create a legal obligation for persons who are not

³⁴ *Id.* at n.10.

³⁵ 865 F. 2d at 423 ff. (Selya, J., dissenting).

³⁶ Recall that § 1397(k)’s title was “Continuation of common law liability.” Neither the majority opinion nor the dissent in *Wood* explicitly addressed the possible significance of the word “Continuation,” although in effect that was the ground of their disagreement.

parties to the lawsuit—and thus does not create a “standard” that offends section 1392(d)?

Intervening years brought varying theories and results. In the later federal circuit court opinions facing the specific tension between sections 1392(d) and 1397(k), the *Wood* majority’s reasoning about Congress’s knowledge of *where common law liability was at the moment* had been rejected in favor of Judge Selya’s observation as to *where it was going (and had by now arrived)*, i.e., that the statute had been “passed in the midst of . . . turbulent change.” All agreed, however, with the *Wood* result—that common law actions against automobile manufacturers specifically for failure to equip their cars with airbags were impliedly pre-empted. Most relied on the specific congressional turmoil over passive safety devices reflected in the 1974 amendments and subsequent developments; this turmoil, they concluded, warranted an implied pre-emption conclusion, which they grounded in the way design defect liability would frustrate the “slow change” purposes of the standard.³⁷ Later, the Ninth Circuit would sidestep this disagreement with an interpretation of its own—that section 1397(k) preserved common law “design defect” liability only respecting those matters “that States have authority to impose”—where no governing federal standard existed, or a required device could be shown to have been defectively designed to meet a governing federal standard.³⁸ In such cases, section 1397(k) would preclude the affirmative defense of federal regulatory compliance. But the section could *not* be invoked to evade section 1392(d)’s express preemption of state authority to create a design standard that differed in any respect from an applicable federal standard.

In state high courts, results were mixed. Some state courts agreed that design defect suits

³⁷ Taylor v. General Motors Corp., 875 F.2d 816 (11th Cir. 1989); Pokorny v. Ford Motor Co., 902 F.2d 1116 (3d Cir. 1990); Kitts v. General Motors Corp., 875 F.2d 787 (10th Cir. 1989).

³⁸ Harris v. Ford Motor Co., 110 F.3d 1410, 1415 (9th Cir. 1997).

based on the absence of airbags were pre-empted.³⁹ Beginning in 1995, however—seven years after *Wood* and four years after Congress had legislatively required universal airbags as of 1998—five found such suits permitted, two in acknowledged disagreement with the very federal circuits in which their states were located.⁴⁰ None of these courts paid any attention to the possible implications of “Continuation” in section 1397(k)’s title; all were writing three decades after the language had been enacted. By this time not only had “design defect” become a settled basis for liability and had airbags been made a federal requirement for all cars, but a 1994 recodification of the Safety Act (disclaiming amendatory purpose) had also removed the word “Continuation” from the statute books.⁴¹ And, understandably, all these courts put a good deal of emphasis on the federalism considerations—only indirectly relevant to District of Columbia citizens and a District of Columbia accident such as the one in *Geier*—that argue for preserving state authority to regulate in traditional spheres of state authority, absent clear decision by, or inevitable conflict with, federal authority. In doing so, they put to the side the changed circumstances of common law authority in an age of statutes and regulation.

The Supreme Court’s Preemption Jurisprudence

The Supreme Court had declined to grant certiorari over early cases presenting the 1392(d)-1397(k) tension. Yet the Justices gave some impetus to certain state decisions, and hope

³⁹ *Culluci v. GMC*, 706 A.2d 806 (Pa. 1998); *Cooper v. GMS*, 702 So.2d 428 (Miss. 1997).

⁴⁰ *Ford Motor Co. v. Tebbetts*, 665 A.2d 345 (N.H. 1995), *cert. denied*, 516 U.S. 1072 (1996) (in conflict with *Wood*); *Wilson v. Pleasant and General Motors Corp.*, 660 N.E.2d 327 (Ind. 1995); *Munroe v. Galati*, 938 P.2d 1114 (Ariz. 1997) (in conflict with *Harris*, in note 38 *supra*); *Minton v. Honda of America Mfg., Inc.*, 684 N.E.2d 648 (Ohio 1997); *Drattel v. Toyota Motor Corp.*, 699 N.E.2d 376 (N.Y. 1998).

⁴¹ When Congress recodified the Safety Act, with the usual disclaimers about changing legal substance, it placed both § 1392(d) and § 1397(k) in a new section entitled “Relationship to other laws,” 49 U.S.C. § 30103. It put § 1392(d) in 49 U.S.C. § 30103(b), labeled “Pre-emption,” and § 1397(k) in a different subsection, 49 U.S.C. § 30103(e), labeled “Common law liability.” See Pub. L. 103-272, § 1(e), 108 Stat. 943.

to the Geiers' attorneys, by a series of decisions on pre-emption issues arising in readily graspable factual circumstances that well fit the emerging common law on strict liability:—

- a smoker's suit against cigarette manufacturers that defendants claimed had been pre-empted in good part by congressional provisions on required warning labels;
- a suit against a railroad for an accident involving a fast-moving train at an unguarded grade crossing, arguably precluded by federal regulation of grade crossing hardware and train speed;
- a suit against truck manufacturers whose trucks, lacking anti-lock braking systems, had jack-knifed into plaintiffs' cars when making emergency stops, when a NHTSA standard that would have required such systems had been judicially suspended as neither reasonable nor practicable;
- an action against a pacemaker manufacturer for the failure of a pacemaker whose design had been provisionally approved by the federal Food and Drug Administration, an agency whose standards and requirements enjoy statutory protection from state variation similar to section 1392(d).

Cipollone v. Liggett Group, Inc.,⁴² the cigarette case, was the first of these, decided by a badly fractured Court late in June of 1992. Congress's attention to the health impacts of cigarette smoking first generated a federal statute in 1965; expressing concern for "commerce and the national economy" as well as smoker health, it defined warnings required on cigarette packs and expressing for it provided in part as follows:

⁴² 505 U.S. 504 (1992).

“§ 5. Pre-emption

“(a) No statement relating to smoking and health, other than the statement [‘CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH’], shall be required on any cigarette package.

“(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”⁴³

Amendments in 1969 both strengthened the warning label by substituting “is dangerous” for “may be hazardous” and banned over-the-air (but not print) advertising; but these amendments also broadened § 5(b):

“(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”⁴⁴

While this change left the federal FTC free to regulate print advertising (which it subsequently did), did it also serve to control how state courts, using common-law “failure to warn” and “design defect” doctrine, could treat lawsuits to redress lung cancer injuries?

A majority of the Court, with Justice John Paul Stevens writing the lead opinion, readily concluded that the language of the 1965 provision precluded only requirements that packages (or advertising) use competing verbal formulas, and did not pre-empt state common law actions. In the course of getting this far, the majority committed itself to propositions about the impact of express statutory provisions on pre-emption that suggested a narrow reading for section 1392(d). Acknowledging that pre-emption could ordinarily be either express or implied, the opinion

⁴³ Section 5 of the Federal Cigarette Labeling and Advertising Act, P.L. 89-92, 79 Stat. 282, 283.

⁴⁴ Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87, as amended, 15 U. S. C. §§ 1331-1340.

appeared to reason that these two possibilities were mutually exclusive:

“In our opinion, the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in § 5 of each Act. When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a ‘reliable indicium of congressional intent with respect to state authority,’ *Malone v. White Motor Corp.*, 435 U.S. at 505, ‘there is no need to infer congressional intent to pre-empt state laws from the substantive provisions’ of the legislation. *California Federal Savings & Loan Assn. v. Guerra*, 479 U.S. 272, 282 (1987) (opinion of Marshall, J.). Such reasoning is a variant of the familiar principle of *expressio unius est exclusio alterius*: Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.”⁴⁵

When it came to saying what the 1969 amendment to section 5(b) meant, however, the Court fractured badly. Justices Stevens, Sandra Day O’Connor, Byron White, and Chief Justice William Rehnquist found it much broader; “requirements or prohibitions . . . imposed under State law” reaches past “statement,” and “with respect to the advertising or promotion” captures more than “in the advertising.” Now the common law was in range:

“The phrase ‘no requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, ‘[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.’ *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). . . .

“[C]ommon-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose ‘requirements or prohibitions.’ . . . [I]t is the essence of the common law to enforce duties that are either affirmative *requirements* or negative *prohibitions*. . . . At least since *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), we have recognized the phrase ‘state law’ to include common law as well as statutes and regulations.”⁴⁶

The plurality of four found that some elements of the plaintiffs’ “failure to warn” claims

⁴⁵ 505 U.S. at 517 (majority opinion).

⁴⁶ *Id.* at 521-22 (Stevens, J., plurality opinion).

depended on asserted defendant failures in advertising or promotion and were therefore pre-empted; yet it concluded that other claims might rely only on testing or research practices unrelated to advertising or promotion, and therefore were not pre-empted. “Breach of warranty” claims that might seem to rely on representations were not pre-empted, because those representations had not been *required* by state law and the gravamen of those claims (the question of their falsity in quasi-contractual relationships) was just a matter between the parties; relief if granted would be occasioned by the falsity, not by the breach of any state-imposed duty to speak. Similar analysis defeated some but not all of plaintiffs’ claims of fraudulent misrepresentation.

Three Justices (Harry Blackmun, Anthony Kennedy, and David Souter) would have found much less pre-emption than this “entirely unsatisfactory”⁴⁷ compromise. Pre-emption must be “clearly . . . mandated by Congress’ language”⁴⁸; emphasizing both the majority’s suggestion that express statutory language addressing pre-emption made it unnecessary to consider implied pre-emption and the importance of respecting state sovereignty, they concluded that the language of section 5, even as amended, should not be taken to reach state common-law damage actions.

“[T]he question whether common-law damages actions exert a regulatory effect on manufacturers analogous to that of positive enactments—an assumption crucial to the plurality’s conclusion that the phrase ‘requirement or prohibition’ encompasses common-law actions—is significantly more complicated than the plurality’s brief quotation from *San Diego Building Trades Council v. Garmon* would suggest. . . . Although an award of damages by its very nature attaches additional consequences to the manufacturer’s continued unlawful conduct, no particular course of action (*e.g.*, the adoption of a new warning label) is required. A manufacturer found liable on, for example, a failure-to-warn claim may respond in a number of ways. It may decide to accept damages awards as a cost of doing business and not alter its behavior in any way. . . . [T]he Court . . . has declined on several recent occasions to find the regulatory effects of state tort law direct or

⁴⁷ *Id.* at 531 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting).

⁴⁸ *Id.*

substantial enough to warrant pre-emption”⁴⁹

Justices Antonin Scalia and Clarence Thomas, equally unhappy with the compromise, would have found universal pre-emption under section 5(b) as amended. Statutes like section 5(b) were to be interpreted “neither narrowly nor broadly, but in accordance with their apparent meaning. If we did that job in the present case, we would find, under the 1965 Act, pre-emption of petitioner’s failure-to-warn claims; and under the 1969 Act, we would find pre-emption of petitioner’s claims complete.”⁵⁰ No “plain-statement” rule is appropriate. Moreover, the suggestion apparently embraced by seven Justices, that

“once there is an express pre-emption provision, . . . all doctrines of implied pre-emption are eliminated . . . works mischief. . . . If taken seriously, it would mean, for example, that if a federal consumer protection law provided that no state agency or court shall assert jurisdiction under state law over any workplace safety issue with respect to which a federal standard is in effect, then a state agency operating under a law dealing with a subject other than workplace safety (*e.g.*, consumer protection) could impose requirements entirely contrary to federal law—forbidding, for example, the use of certain safety equipment that federal law requires. To my knowledge, we have never expressed such a rule before, and our prior cases are inconsistent with it.”⁵¹

This badly fractured set of opinions opened new doors for air-bag “design defect” liability, while also possibly supporting some defense arguments. In the Safety Act, Congress had used the word “standard,” a term much more clearly pointed to statutes and rules than “requirement or prohibition”; and it specifically addressed state legislative and executive authority in its explicit attention to pre-emption. In this Act, unlike the cigarette statutes, Congress had with equal explicitness preserved common law claims. Even with Justices Blackmun and White replaced by

⁴⁹ *Id.* at 536-37.

⁵⁰ *Id.* at 544 (Scalia, J., concurring in the judgment in part and dissenting in part).

⁵¹ *Id.* at 547-48.

Justices Stephen Breyer and Ruth Bader Ginsburg, there appeared to be five solid votes for the proposition that Congress's choice of words, narrowly construed, controlled the issue. And significant doubts had been raised, to which the Safety Act's savings clause gave force, whether common law verdicts should be equated with regulatory law.

CSX Transportation, Inc. v. Easterwood,⁵² decided the following Term, dealt with provisions of the Federal Railroad Safety Act of 1970. That statute declared that “laws, rules, regulations, orders, and standards relating to railroad safety shall be nationally uniform to the extent practicable,” but permitted states to regulate railroad safety issues “until such time as the Secretary has adopted a . . . regulation . . . covering the subject matter of such State requirement.” If she had done so, states were permitted even then to adopt safety standards more stringent than the federal requirements “when necessary to eliminate or reduce an essentially local safety hazard,” if those standards were compatible with federal law and would not unduly burden interstate commerce.⁵³

Plaintiff's husband had been killed at a railroad crossing lacking warning signals, by a train traveling through town at between 32 and 50 mph, and she sued under state negligence law, claiming the absence of warning signals and excessive speed. The Secretary had *not* used the Railroad Safety Act to regulate crossing guards at the railroad crossing in question,⁵⁴ but *had* classified the track there as safe for 60 mph use; the characteristics considered in classifying it did not include whether the track would be in town or country.

⁵² 507 U.S. 658 (1993).

⁵³ 45 U.S.C. § 434.

⁵⁴ Some crossing guard regulations, also from the Department of Transportation, formed an element of the requirements for state access to federal highway funds; but this funding mechanism had no bearing on the Railroad

The Justices unanimously agreed with Justice White’s opinion setting general principles: courts should not find pre-emption unless it is “the clear and manifest purpose of Congress,” as shown by statutory text and structure; “[l]egal duties imposed on railroads by the common law fall within the scope of these broad phrases [‘law, rule, regulation, order, or standard relating to railroad safety,’]”; yet the federal statute’s use of the restrictive term “covering” “indicates that pre-emption will lie only if the federal regulations substantially subsume the subject matter of the relevant state law.”⁵⁵ The Court was unanimous, too, that the negligence claim respecting the absence of a warning signal was *not* substantially subsumed in the Secretary’s regulations, and therefore was not pre-empted.

For seven Justices, however, the Secretary’s speed regulations did “cover” the “excessive speed” claim, for those regulations took the hazards posed by track conditions into account; although the hazards considered had to do with derailment risks, and not the variable dangers associated with population density nearby, the pre-emption question was governed by their coverage and not their purpose. Nor could the application of common law negligence liability, uniform throughout Georgia, be regarded as a “local” safety rule turning on unique local conditions. Justice Thomas, for himself and Justice Souter, dissented from this element of the Court’s opinion; for them, a regulation calibrating speed limits to “*the nature of the track on which [the trains] operate*”⁵⁶ and not the community through which they ran, did not “cover” a claim connecting speed to grade crossing safety. “To read the Secretary’s existing maximum speed regulation as encompassing safety concerns unrelated to track characteristics . . . negates

Safety Act’s pre-emption provision.

⁵⁵ *Easterwood*, 507 U.S. at 664.

⁵⁶ *Id.* at 676 (Thomas, J., dissenting in part) (emphasis in original).

Congress' desire that state law be accorded 'considerable solicitude.'"⁵⁷

For practitioners, these two opinions suggested a considerable opening for “airbag” actions. The Safety Act’s express pre-emption clause was much more narrowly worded than those considered by the Court in *Cipollone* and *Easterwood*. Unlike tobacco legislation, the Safety Act had an express savings clause preserving common law claims; unlike the Railroad Safety Act, that clause was independent of the pre-emption provision. While acknowledging that common law rules could operate as statutes or regulations did, the opinions nonetheless left that equation open to some doubt. Both sets of opinions had stressed the importance of congressional clarity if federal law was to displace state law in traditional state areas. In 1994, “Continuation” had disappeared from the Safety Act’s saving clause unremarked, and even the *Wood* court, while reasoning from the state of the common law when Congress acted in 1966, had found no *express* pre-emption of state common law remedies. No other court had followed its path, and now state courts, encouraged by these decisions and professional commentary,⁵⁸ began to find “design defect” liability.

Two years later, the grant of certiorari in *Freightliner Corp. v. Myrick*⁵⁹ suggested that the

⁵⁷ *Id.* at 679.

⁵⁸ The Lexis database for Law Reviews, CLE, Legal Journals and Periodicals reports 317 hits for “Cipollone” between January 1, 1992 and January 1, 1996. Eighteen have “Cipollone” in their title, mostly involving cigarette litigation or pre-emption under the Federal Insecticide, Fungicide and Rodenticide Act, but including Kurt B. Chadwell, *Automobile Passive Restraint Claims Post-Cipollone: An End to the Federal Preemption Defense*, 46 Baylor L. Rev. 141 (1994); Mark C. Coulter, Comment, *The Impact of Cipollone and Federal Preemption on State Common-law Tort Actions in Missouri’s State and Federal Courts*, 64 UMKC L. Rev. 357 (1995); Jeffrey R. Stern, *Preemption Doctrine and the Failure of Textualism in Cipollone v. Liggett Group*, 80 Va. L. Rev. 979 (1994); and John A. Chatowski, Note, *Cipollone and the Clear Statement Rule: Doctrinal Anomaly or New Development in Federal Preemption?*, 44 Syracuse L. Rev. 769 (1994) (visited June 23, 2009).

⁵⁹ 514 U.S. 280 (1995).

Court might be ready to address the tension between sections 1392(d) and 1397(k).⁶⁰ In two cases, tractor trailer trucks attempting sudden stops in Georgia had jackknifed into oncoming traffic, killing or severely injuring drivers; the trucks lacked anti-lock braking systems (ABS), and plaintiffs sought to establish state common law “design defect” liability. In 1970 NHTSA in fact had issued a standard that set required stopping distances and vehicle stability parameters for trucks; in effect, meeting these parameters required ABS systems. But manufacturers, worried about the safety and performance of the systems then available, had challenged the requirements in court. In 1978, the Ninth Circuit had found the standard “neither reasonable nor practicable at the time it was put into effect,” and ordered it suspended until NHTSA could amass data showing its propriety.⁶¹ NHTSA complied. While continuing to advise manufacturers what it regarded as reasonable standards for acceptable truck braking performance, NHTSA had not at the time of the accident taken any action to reinstate a governing standard. For this reason, Justice Thomas wrote for a near-unanimous Court,⁶² section 1392(d) did not apply, and states remained free to establish their own safety standards. Congress having indicated no purpose wholly to occupy the field of motor vehicle safety, and there being no federal standard for state law to conflict with or defeat, preemption simply was not an issue. This reasoning made it unnecessary to consider the relationship of sections 1392(d) and 1397(k).⁶³

⁶⁰ See, e.g., “When Does Federal Law Trump State Law? Does a Broadly Worded Savings Clause Permit State Suits that Subvert the Goals of a Federal Statute?,” in ABA, *Preview of United States Supreme Court Cases*, 5 Preview 234 (1995).

⁶¹ *Paccar, Inc. v. NHTSA*, 573 F.2d 632, *cert. denied*, 439 U.S. 862 (1978).

⁶² Without explanation, Justice Scalia concurred only in the result.

⁶³ In a footnote, the Court remarked:

“Because no federal safety standard exists, we need not reach respondents’ argument that the term ‘standard’ in 15 U.S.C. § 1392(d) pre-empts only state statutes and regulations, but not common law. We also need not address

Significantly for the developments we are following, the opinion was at pains to reject the reading many had given *Cipollone*, that explicit statutory language on pre-emption exhausted the issue, precluding any implied pre-emption inquiry. “The fact that an express definition of the pre-emptive reach of a statute ‘implies’—*i.e.*, supports a reasonable inference—that Congress did not intend to pre-empt other matters,” the Court now declared, “does not mean that the express clause entirely forecloses any possibility of implied pre-emption. . . . At best, *Cipollone* supports an inference that an express pre-emption clause forecloses implied pre-emption; it does not establish a rule.”⁶⁴

While this opinion thus diminished the importance of *Cipollone* by reaffirming the availability of implied pre-emption in the face of express, its affirmation of state “design defect” liability in the face of federal regulatory uncertainty was a hopeful sign for plaintiffs’ attorneys. The impediments Congress had put in the way of a federal airbag standard in 1974, and the equivocation of the Department in the years following, created a situation not unlike that in *Freightliner*. The federal courts following *Woods* had taken these developments as a reason *for* finding pre-emption. Did *Freightliner* give them weight *against* such a finding? Must Congress’s and the Department’s prior uncertainty about a uniform national standard (now resolved in safety’s favor!) be taken to have foreclosed use of a now-widespread common law analysis grounded in a well-known and entirely feasible safety improvement of unquestionable importance?

respondents’ claim that the saving clause, § 1397(k), does not permit a manufacturer to use a federal safety standard to immunize itself from state common-law liability.”

514 U.S. at 287 n.3.

⁶⁴ *Freightliner*, 514 U.S. at 288-89.

Just a year later, the Court returned to pre-emption in *Medtronic, Inc. v. Lohr*,⁶⁵ a state common law “manufacturing defect,” “design defect” and “failure to warn” action against the manufacturer of a pacemaker subject to FDA regulation. The pacemaker had failed in operation, substantially injuring and imperiling the plaintiff. In the 1976 medical device amendments, adopted *after* “design defect” and “failure to warn” liability had become an established element of the common law landscape, Congress had addressed pre-emption in the following terms:

“21 U.S.C. § 360k. State and local requirements respecting devices

“(a) General rule—Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

“(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

“(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

“(b) Exempt requirements—Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if —

“(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

“(2) the requirement—

“(A) is required by compelling local conditions, and

“(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.”

FDA regulations were in place, providing that state requirements were not pre-empted unless the FDA had set “specific requirements applicable to a particular device.”⁶⁶ One question,

⁶⁵ 518 U.S. 470 (1996).

⁶⁶ 21 C.F.R. § 808.1(d) (1995).

then, was whether a state common law rule could constitute the “requirement” subsection (a) made subject to pre-emption unless exempted under the procedures of subsection (b). The relevant statute lacked a savings clause. Thus, another question was this: if a common law rule did *not* constitute a “requirement” for purposes of subsection (a), did the statutory language define the exclusive field of pre-emption, or might the common law rule nonetheless be pre-empted if it conflicted in fact with the federal regime? As in *Cipollone*, Justice Stevens wrote an opinion that was only in limited respects an opinion of the Court. His opinion found less pre-emption in the case than the minority would have. Those who joined his plurality opinion were, on the whole, those who had found less pre-emption in *Cipollone* than he had;⁶⁷ those who now differed with him were, on the whole, those who had agreed with him in *Cipollone* or had found a greater degree of pre-emption in that case.⁶⁸

Justice Stevens’ opinion appears to have been driven by an essentially practical consideration. The Medical Device Act ostensibly made medical devices such as the pacemaker in question subject to a rigorous FDA clearance process.⁶⁹ FDA’s limited resources, however, had led Congress to permit it provisionally to grandfather devices long on the market—even those classed at the highest level of importance and risk—until such time as the rigorous statutory process could be completed. Congress had also created a summary⁷⁰ clearance process for

⁶⁷ Justices Kennedy, Souter and Ginsburg joined all parts of Justice Stevens’s opinion; Justice Breyer provided the necessary fifth vote. Justices Kennedy and Souter had found virtually no pre-emption in *Cipollone*, and Justices Breyer and Ginsburg were new to the Court.

⁶⁸ Chief Justice Rehnquist and Justice O’Connor had fully subscribed to *Cipollone*; Justices Scalia and Thomas had found essentially universal pre-emption in the earlier case.

⁶⁹ The Court reported that FDA staff averaged 1200 hours spent on each such clearance. 518 U.S. at 477.

⁷⁰ Estimated at 20 hours per clearance. *Id.* at 479.

devices that were “substantially equivalent” to those thus permitted to stay on the market pending the rigorous process. The flood of new medical devices and the continuing limitation of FDA resources meant that the overwhelming majority of devices—including the one that had failed the plaintiff here —were being brought on the market as “substantially equivalent,” and thus received only glancing federal safety review. Once again, consumer protection had been compromised by congressional equivocation—now, with the resources FDA needed to do its job. And it was this barely considered regulatory approval that Medtronic was relying upon in claiming wholesale pre-emption of state common law liability. For Justice Stevens and those who joined him, this result was both “singularly”⁷¹ and “spectacularly”⁷² odd. “Medtronic’s sweeping interpretation of the statute would require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the Lohrs’ alleged injuries.”⁷³

The basic disagreement among the Justices in *Medtronic* was how to understand the statutory term “requirement” in relation to common-law claims. The FDA’s regulations construing section 360k, while asserting its applicability to court decisions “having the force and effect of law,” limited pre-emption to situations in which “the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug

⁷¹ *Id.* at 487 (Stevens, J., plurality opinion).

⁷² *Id.* at 491 (Stevens, J., plurality opinion).

⁷³ *Id.* at 488-89 (Stevens, J., plurality opinion). In *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), where another Medtronic device had in fact undergone the rigorous clearance process, all Justices save Justice Ginsburg would agree that § 360k precluded a state common law action premised on the device’s inadequacy.

Administration requirements.”⁷⁴ For the plurality (the Justices joining all of the Stevens opinion), no such *specific* requirements existed, and it would be “rare indeed for a court hearing a common-law cause of action to issue a decree that has ‘the effect of establishing a substantive requirement for a specific device.’ Until such a case arises, we see no need to determine whether the statute explicitly pre-empts such a claim.”⁷⁵

Justice Breyer, also drawing on the FDA regulation and agreeing completely with the plurality’s findings against pre-emption of any of the particular claims involved *in this case*, subscribed to Justice O’Connor’s partial dissent insofar as it expressed a greater willingness to find possible pre-emption of common law claims in the statutory reference to “requirement.” “One can reasonably read the word ‘requirement’ as including the legal requirements that grow out of the application, in particular circumstances, of a State’s tort law,”⁷⁶ and he was unpersuaded that such cases would be rare. For Justice Breyer, however, the FDA regulation’s “specific” warranted the majority’s particular conclusions, and so he concurred in its judgment and most elements of its opinion.

Justice O’Connor’s partial dissent was emphatic that the case presented questions *only* of statutory interpretation, and that these questions were questions for the Court. Common-law rules could constitute “requirements” subject to pre-emption (thus, with Justice Breyer, establishing a majority on this point); she and the three Justices joining her would have ignored the FDA’s narrowing regulation on the point since “[t]he statute makes no mention of a requirement of

⁷⁴ 21 C.F.R. § 808.1(d) (1995). Justice Stevens’s opinion quoted the provision’s full text at length, 518 U.S. at 499 (majority opinion).

⁷⁵ 518 U.S. at 502-03 (Stevens, J., plurality opinion) (quoting 21 CFR § 808.1(d)(6)(ii) (1995)).

⁷⁶ *Id.* at 504 (Breyer, J., concurring in part and in the judgment).

specificity, and there is no sound basis for determining that such a restriction on ‘any requirement’ exists.”⁷⁷ For her,

“Some, if not all, of the Lohrs’ common-law claims regarding the manufacturing and labeling of Medtronic’s device would compel Medtronic to comply with requirements different from, or in addition to, those required by the FDA. The FDA’s Good Manufacturing Practice (GMP) regulations impose comprehensive requirements relating to every aspect of the device-manufacturing process . . . [and t]he Lohrs’ common-law claims regarding manufacture would, if successful, impose state requirements ‘different from, or in addition to,’ the GMP requirements, and are therefore pre-empted. In similar fashion, the Lohrs’ failure to warn claim is pre-empted by the extensive labeling requirements imposed by the FDA. . . . These extensive federal manufacturing and labeling requirements are certainly applicable to the device manufactured by Medtronic. Section 360k(a) requires no more specificity than that for pre-emption of state common-law claims.”⁷⁸

If “requirement” could reach common law outcomes, in a statute so worded as to point directly at state political actors, so perhaps could the “safety standard” of section 1392(d); yet the Medical Devices Act lacked a savings clause equivalent to section 1397(k). One might also have thought *Medtronic* a case in which an effective majority was again equivocating about the need to go past a statute expressly setting pre-emption parameters.

In automobile safety cases, the statute seemed to distinguish between “safety standard” and common law liability. *Freightliner* and *Medtronic* did not discourage state courts from permitting “design defect” actions in airbag cases, but for one reason or another the Supreme Court continued to seem disinterested in the conflict between state courts and those federal circuits which had confronted the issue. Its opinions continued to emphasize the importance of federalism considerations in thinking about pre-emption, without really addressing the place of

⁷⁷ *Id.* at 512 (O’Connor, J., concurring in part and dissenting in part).

⁷⁸ *Id.* at 513-14.

the common law in an age of statutes. Some sense of that place, one might think, animated its willingness to find in federal statutes' use of words like "requirements" a common law reference, but that was all.

The *Geier* Case: Argument, Decision, Aftermath

The Geiers sought relief in federal court under the common law of the District Columbia. Thus, for them at least, the "pre-emption" issues had no federalism components. The whole question would be whether judge and jury would be permitted to do what local legislative and administrative bodies could not. Unsurprisingly, perhaps, first trial Judge William B. Bryant and then the D.C. Circuit⁷⁹ made short shrift of their claims, the latter relying essentially on the reasoning of *Taylor* and *Pokornoy*:⁸⁰ if it could not find express pre-emption, given section 1397(k) understood as embracing design defect actions, it found pre-emption implied by the "tortured history"⁸¹ of the airbag standard and NHTSA's consequent specific determination (with reasons) of the need to go slow. Common law rulings could be understood as "standards" and even if their general survival was assured by the savings clause, they were impliedly pre-empted by that determination. A petition for certiorari followed, and was granted with unusual alacrity. Ordinarily, once the Court recesses for the summer, orders on petitions for certiorari do not appear until shortly before its next Term resumes on the first Monday of October. The order granting certiorari in this case was issued September 10, 1999, with a somewhat accelerated briefing schedule, perhaps reflecting a light fall docket for the Court and thus contemplating

⁷⁹ 166 F.3d 1236 (1999).

⁸⁰ These cases are cited in note 37 *supra*.

⁸¹ 166 F.3d at 1242.

December argument.

How should plaintiffs' attorneys have briefed the case, given the perhaps equally "tortured history" of pre-emption claims in recent years? All the Justices participating in *Freightliner* and *Medtronic* were still sitting. *Cipollone* had been disavowed, but a majority still seemed quite wedded to express statutory language, and the Geiers had the benefit of an express savings clause. Given that clause and that attitude, could one avoid the Court's usual disposition to regard common law outcomes as possible "requirements"? Did "standard" open the door to a narrower understanding of section 1392(d)? With a majority disposed to limit pre-emption to conflicts that were specific, might there be a way of characterizing the conflict here in terms that seemed broadly, not narrowly, to disable the common law?

Fortunately for the Geiers, the Department of Transportation, although generally supporting Honda, took any argument from *Wood* or *Harris* in the nature of express pre-emption off the table. The Secretary of Transportation, it reported in its brief, "has long taken the view that, although state legislatures and administrative agencies may not adopt a safety standard . . . state courts are not necessarily precluded from entering tort judgments that a vehicle was defectively designed . . . [reflecting the] congressional compromise."⁸² The Department offered no documentation, but the concession undercut the argument of an *amicus*, the Alliance of Automobile Manufacturers, that pre-emption here *was* express: an argument claiming "the superiority of common-law liability as a mode of safety regulation . . . cannot at the same time take the position that the standards on which such liability is premised are not 'safety

⁸² Brief for the United States as Amicus Curiae Supporting Affirmance, *Geier v. American Honda Motor Co.* (Supreme Court Docket No. 98-1811), at 8-9.

standards.’”⁸³ Why would the Secretary have conceded that the common law liability for the “Continuation” of which Congress had provided in section 1397(k) was more than the “manufacturing defect” liability that had been common ground in 1966, when Congress enacted this provision?

Indeed, as noted above,⁸⁴ one phrase in the very extensive statement of basis and purpose that accompanied Secretary Dole’s 1984 Standard 208 could be read to have welcomed the possibility of design defect liability as a goad to manufacturers to install airbags. As the Secretary well knew, even though the technology had been at hand for well over a decade and its safety benefits were well established, only a handful of manufacturers were beginning to offer airbags on high-end cars. Absent a federal standard addressing passive design elements such as airbags—and until she acted, none validly had—section 1392(d) posed no possible barrier to “design defect” actions such as the Geiers’. None had yet been successfully brought, but surely automotive counsel were aware of the risk. In observing that “potential liability for any deficient systems” would serve as an encouragement to move past the cheapest passive restraint alternative, automatic seatbelts,⁸⁵ wasn’t the Secretary signaling an understanding that “design defect” common law liability for failure to choose airbags was available? In briefing the pre-emption question in court, the United States had consistently taken the position it would take in *Geier*, that such liability was not expressly pre-empted, but was impliedly pre-empted as interfering with the Secretary’s carefully thought out policy for introducing passive restraints. That program

⁸³ Brief of the Alliance of Automobile Manufacturers and the Association of International Automobile Manufacturers, Inc., as *Amici Curiae* in Support of Respondents, *Geier v. American Honda Motor Co.* (Supreme Cour Docket No. 98-1811), at 17.

⁸⁴ See *supra* note 25 and accompanying text.

⁸⁵ *Id.*

affirmatively permitted both manufacturer choice and gradualism in the hope of winning the public acceptance that 1974's legislative debacle had proved absent. But these many representations made in the course of litigation might be undercut by what the Secretary had said in explaining her reasons for adopting the rule.⁸⁶

It was with this proposition that counsel for the Geiers led off his oral argument,⁸⁷ and the

⁸⁶ One of the propositions encountered again and again in a course on Administrative Law is that official explanations made by responsible officials as a formal element of an administrative action have a credibility that is lacking in litigation briefs or affidavits.

⁸⁷ "MR. BRYANT: Mr. Chief Justice, and may it please the Court:

The petitioners claim that the 1987 Honda Accord in this case was defectively designed under District of Columbia common law because it did not have an airbag in addition to a manual lap belt and shoulder harness.

There are two primary reasons why these common law claims are not preempted here.

First, Secretary Dole viewed these common law claims as furthering, rather than frustrating, the policies underlying standard 208.

Second, even if Secretary Dole had wanted to pre-empt these common law claims, Congress expressly denied her the power to do so.

Now, the reason I say that petitioners' claims were seen by Secretary Dole as furthering the policies under standard 208 is because she herself said that. In explaining the rationale for adopting the rule, she said that she would rely on, quote, the potential liability for deficient systems, end quote, to make sure that the manufacturers did not all put in the cheaper passive restraint, automatic seatbelts, and instead started putting in more of the more expensive passive restraint airbags. That is her statement.

In addition, under the section entitled Product Liability—

JUSTICE SCALIA: Where does—where does that appear? . . .

MR. BRYANT: 49 Federal Register 29,000.

JUSTICE SCALIA: Which is the statement of basis and purpose for the rule?

MR. BRYANT: Yes. It is in the preamble to the rule under the heading—under the heading Rationale for Adopting the Rule.

JUSTICE SOUTER: I find the statement you just quoted a troubling one for the other side, I agree. But I still have difficulty in accepting it as having the significance for your side that you want because it seems to me that if, in making that statement, she in effect was alluding to the significance or the power of the common law to, in effect, adopt the very rule that she was declining to adopt—i.e., you got to have the airbags—then she was, in effect, saying I'm relying upon the common law to thwart the very judgment that I am making now. And that seems very odd. What do you make of that?

transcript of that argument suggests, more strongly than the opinions in the case, that it was an issue at the heart of the Court’s concerns. If he could succeed in persuading the Court that the common law liability he was seeking to establish should be understood valuably to supplement the Secretary’s purposes, rather than to frustrate them, any “implied pre-emption” argument would be defeated. Counsel for the United States, appearing in support of Honda, addressed virtually the whole of his argument to the proposition that eventually prevailed—that the Secretary, acting in the shadow of the years of legislative and administrative equivocation that preceded her, had affirmatively opted for permitting manufacturers (and the consuming public) choice. — Such a federal policy clearly would be frustrated by a common-law rule effectively requiring that one specific choice had to have been made.

The Geiers’ counsel’s second argument, that “even if Secretary Dole had wanted to pre-empt these common law claims, Congress expressly denied her the power to do so,” seemed to produce greater resistance. The Court understood the claim to be that section 1397(k) was a congressional judgment completely precluding pre-emption of common law liability. Justice Breyer asked about impossibility: suppose the Secretary had *required* airbags in all cars (as by

MR. BRYANT: Well, I don’t think she saw it that way at all. I think we have to start with the understanding that Secretary Dole found and all of the manufacturers admitted that the safest, best system was exactly the one that we seek to have installed in this case, an airbag plus a manual lap belt and shoulder harness.

She also was facing this Court’s decision remanding the last rule that was issued as arbitrary and capricious because it didn’t consider requiring airbags in all cars. Yet, she chose not to order airbags in all cars because she was concerned about cost considerations. She was concerned about manufacturer resistance, public acceptability, technological problems, and stifling innovation.

The reason she wanted tort liability to kick in, however, was because she knew—and she said it clearly—that if she simply required passive restraints generally, almost all the manufacturers would put in automatic seatbelts. . . .

This transcript, as well as the many briefs filed in the case, are available in the commercial data bases, e.g., 1999 U.S. Trans. LEXIS 63 (oral argument); 1999 U.S. S. Ct. Briefs LEXIS 1301 (briefs). *Listening* to the oral argument (at http://www.oyez.org/cases/1990-1999/1999/1999_98_1811/argument) permits identifying the Justice speaking, and

now had happened), and the parent of a child killed by an airbag's deployment (a not uncommon event that eventually produced a changed standard for front seat passengers) were to bring a common law action asserting that having the airbag in the passenger seat made the car unacceptably unsafe? Counsel seemed unwilling to concede that a common law rule requiring direct violation of the federal standard would be pre-empted, perhaps fearing that he could not persuade the Court to distinguish between impossibility pre-emption and frustration pre-emption; no case had done that. Defense counsel, on the other hand, was able to stress section 1397(k)'s opening words—"Compliance with"—suggesting that the section (like the corresponding language in the Third Restatement of Torts⁸⁸) merely addressed affirmative defenses available in relation to a valid standard, the *Harris*⁸⁹ approach. That would have left room for an argument, for example, that the design of the particular Honda model Ms. Geier was driving was unacceptably unsafe, given the propensity of its seat to break. But the Geiers' counsel was not making arguments about the particulars of this car and this accident, and in the end that may have been his undoing.

All the Justices save Justice Thomas, who rarely asks questions during oral argument, participated in the oral argument, and to this observer at least it would not have been evident from their questions or voice tone how most of them were going to vote. It took them five and a half months after argument to announce their 5-4 decision, ruling for Honda only because NHTSA's affirmative and understandably motivated provisions for gradualism and choice justified the conclusion that plaintiff's theory of the case was impliedly pre-empted. The Court was

hearing inflections. A fine argument, it is an intense conversation almost entirely focused on the tough issues.

⁸⁸ § 4(b), quoted in text at note 28 above.

⁸⁹ See *supra* note 38 and accompanying text.

unanimous that, given the savings clause of section 1397(k), *express* pre-emption could not be found. Implied pre-emption was a different story. Justice Breyer’s majority opinion, like his middle-ground concurrence in *Medtronic*, reflected his skepticism of the “plain meaning” approach the Geiers’ counsel had taken to section 1397(k) and avoided a comprehensive response to the question left open in a *Freightliner* footnote.⁹⁰ Drawing on the Third Restatement’s distinction between “pre-emption” and an affirmative defense,⁹¹ he characterized the section as preserving “those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation *intended to provide [only] a floor.*”⁹² Though it might have been possible to characterize Standard 208 in just this way—the Standard encouraged manufacturers to provide more passive safety than it required—plaintiffs’ argument, as made, would have frustrated its understandably motivated provisions for gradualism and choice. Perhaps an argument specifically framed in terms of a 1987 Honda Accord’s design characteristics, and not more generally, would have found a majority.

Justice Stevens, the author of *Medtronic*, wrote for himself and Justices Ginsburg, Souter and Thomas. Once again less willing to find pre-emption than others, Justice Stevens this time around lost Justice Kennedy’s vote, but gained Justice Thomas’s. Strikingly, given the accident’s location in the District of Columbia (and the arguably greater state interest in having legislative and executive than judicial freedom for innovation), his opinion struck “federalist” themes again and again.⁹³ He argued that there was a “special burden” for congressional clarity when

⁹⁰ See *supra* note 63.

⁹¹ See *supra* text accompanying note 28.

⁹² 529 U.S. at 870 (emphasis added).

⁹³ The recent decision in *Wyeth v. Levine*, next discussed, repeatedly addresses *Geier* as if it had involved conflict

impacting common law development in the pre-emption context, an argument that the majority rejected⁹⁴ as unfounded and confusing. Because congressional clarity was the issue for the dissenters, and indeed Standard 208's governing text was silent on the question, NHTSA's asserted policy objectives fell by the wayside. The dissent thought the objectives actually stated in the statement of basis and purpose would not be frustrated in fact, given NHTSA's preference to have airbags, given the conceded availability of the cause of action before September 1, 1987 (when the revised Standard had taken effect), and given the failures of automobile manufacturers to respond to that incentive then. However, the phrase from the statement of basis and purpose pointing in this direction, that had so animated the oral argument, was barely mentioned.⁹⁵ Rather, the dissent sought to discredit "the Court's unprecedented use of inferences from regulatory history and commentary as a basis for implied pre-emption."⁹⁶

Fast forward, then, to 2009, and the question whether state common law "failure to warn" liability had been pre-empted by FDA approval of a dangerous drug's labelling. In *Wyeth v.*

between state and national authority, rather than the relationship between the actions of political actors (legislatures and executive bodies) and the actions of common law judges and juries. Thus, Justice Thomas's striking characterization of the case: "Applying 'purposes and objectives' pre-emption in *Geier* . . . allowed this Court to vacate a judgment *issued by another sovereign* based on nothing more than assumptions and goals that were untethered from the constitutionally enacted federal law authorizing the federal regulatory standard that was before the Court." 129 S. Ct. at 1215 (emphasis added).

⁹⁴ 529 U.S. at 872-73 (majority opinion). Since a common law rule requiring direct violation of a federal standard would certainly be fall as impliedly pre-empted, so also must one unmistakably preventing or frustrating "the accomplishment of a federal objective." *Id.*

⁹⁵ 529 U.S. at 892 n.5 (Stevens, J., dissenting) ("With one oblique exception, there is no mention, either in the text of the final standard or in the accompanying comments, of the possibility that the risk of potential tort liability would provide an incentive for manufacturers to install airbags."); *id.* at 910 ("Neither Standard 208 nor its accompanying commentary includes the slightest specific indication of an intent to pre-empt common-law no-airbag suits. Indeed, the only mention of such suits in the commentary tends to suggest that they would not be pre-empted. See n. 5, *supra*.").

⁹⁶ *Id.* at 913.

Levine,⁹⁷ a professional musician had to have her arm amputated after a medical technician's misjudgment apparently injected the drug in an artery rather than a vein, in an elbow location where such an error was known to be especially likely. The injection caused her to develop gangrene, forcing the amputation. The FDA-approved warning had in fact indicated this unfortunate possibility among others, but had not in terms forbidden the use of the particularly hazardous intravenous delivery system the technician had chosen.⁹⁸ After some reported incidents of similar outcomes, it and the drug's manufacturer had considered stronger warnings, but the FDA process had not adopted them. The FDA's regulations permitted drug companies to add to warnings in advance of FDA approval when developing information warranted that. For years the FDA had taken the position that "failure to warn" litigation claiming the need for warning supplementary to what it had approved was not pre-empted. Rather, it had argued, compliance with its warning requirements should be taken as evidence of appropriate warning—the position also of the Third Restatement.⁹⁹ Although the statute governing drug approvals

⁹⁷ 129 S.Ct. 1187 (2009).

⁹⁸ "The warning for 'Inadvertent Intra-arterial Injection' stated: 'Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs. . . . Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with Phenergan Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone. When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute. When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily. In the event that a patient complains of pain during intended intravenous injection of Phenergan Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.'"

129 S.Ct. at 1192 n.1.

⁹⁹ See *supra* note 28 and accompanying text.

required submission of label warnings to the FDA for approval, it had no provision suggesting express pre-emption, unlike the 1976 statute governing medical devices dealt with in *Medtronic*. Instead, the Federal Food, Drug and Cosmetic Act [FDCA] has provided since 1962: “Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.”¹⁰⁰ This language not only explicitly recognized the principles of conflict pre-emption, but also arguably limited its scope. As a result, state common law suits had been freely entertained.¹⁰¹ But late in the second Bush Administration, six years *after* the plaintiff had lost her arm, the statement of basis and purpose for a new FDA regulation on labeling sought to change these outcomes. It asserted that the 1962 statute created “both a ‘floor’ and a ‘ceiling,’” with the result that “FDA approval of labeling . . . preempts conflicting or contrary State law.” State common law failure-to-warn claims, the FDA now claimed, “threaten FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.”¹⁰² Evidently, someone in the Administration had read *Geier*. Would pre-emption result?

Now, with Justice Stevens again writing for the Court and numerous opinions again filed, the answer was in the negative. *Geier* figured prominently in all but its author’s (Justice Breyer’s) brief concurrence written “to emphasize the Court’s statement that ‘we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the

¹⁰⁰ Drug Amendments of 1962, § 202, 76 Stat. 793.

¹⁰¹ “By the time Congress enacted the MDA in 1976, state common-law claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation” (citing numerous cases) *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1017 (2008) (Ginsburg, J., dissenting).

¹⁰² 71 Fed. Reg. 3922, 3934-35 (2006).

force of law”¹⁰³—language one could regard as Breyer’s characterization of *Geier* although he did not cite it.¹⁰⁴ The divisive issue, again, was a manufacturer’s claim of implied pre-emption of a well-established state common law remedy on the basis of its potential to frustrate federal policy. This time, the majority agreed with Justice Stevens that no such frustration had been shown. Granted, there were again statements in a regulation’s statement of basis and purpose, and those statements now directly claimed pre-emptive effect. But unlike section 1392(d) in *Geier* or section 360k of the Medical Devices Act at issue in *Medtronic*, the FDCA self-consciously adjured any pre-emptive claim. When in 2000 the agency published the notice of proposed rulemaking that resulted in the statements Wyeth relied on, it said that its proposal would not “not contain policies that have federalism implications or that preempt State law.”¹⁰⁵ It gave no public notice of possible change in this promise before it adopted the rule six years later. The FDA thus had provided states and others no notice or opportunity to comment on the reversal of its “own longstanding position” when, “without providing a reasoned explanation,” it sweepingly claimed pre-emption.¹⁰⁶ In contrast to this “mere assertion,”¹⁰⁷ Justice Stevens explained,

“In *Geier*, the DOT conducted a formal rulemaking and then adopted a plan to phase in a mix of passive restraint devices. Examining the rule itself and the DOT’s contemporaneous record, which revealed the factors the agency had weighed and the balance it had struck, we determined that state tort suits presented an obstacle to the federal scheme. After conducting our own pre-emption analysis, we considered the

¹⁰³ 129 S.Ct. at 1204 (Breyer, J., concurring).

¹⁰⁴ The majority opinion statement Justice Breyer quoted did cite *Geier*. *Id.* at 1203.

¹⁰⁵ 65 Fed. Reg. 81103

¹⁰⁶ 129 S.Ct. at 1201 (majority opinion).

¹⁰⁷ *Id.*

agency’s explanation of how state law interfered with its regulation, regarding it as further support for our independent conclusion that the plaintiff’s tort claim obstructed the federal regime.”¹⁰⁸

Justices Ginsburg and Souter, who had joined his *Geier* dissent, along with Justices Kennedy and Breyer of the *Geier* majority, joined Justice Stevens’s opinion for the Court.

Justice Thomas, the fourth *Geier* dissenter, concurred only in the *Wyeth* judgment. His lonely concurrence extensively and strongly criticized *Geier* and its implied pre-emption holding based on frustration of NHTSA policy.¹⁰⁹ For him, the FDA’s willingness to have companies provisionally strengthen approved warnings and the absence of a statutory provision like section 1392(d) or section 360k precluded any finding of express pre-emption. The language of the FDCA’s savings clause, restricting pre-emption to cases of “direct and positive conflict” meant that only “impossibility” pre-emption was relevant. Congress’s words here, properly understood, precluded pre-emption on the basis of frustration of agency policy, whether the agency acted formally or not.

Dissenting in *Wyeth* were Justice Scalia—often in these cases a supporter of pre-emptive outcomes—and the Court’s two newest Justices, Chief Justice John Roberts and Justice Samuel Alito. Justice Alito wrote for the dissenters. He argued that the “result cannot be reconciled with *Geier* . . . or general principles of conflict pre-emption.”¹¹⁰ Some of Justice Alito’s disagreement with the majority was doubtless prompted by facts strongly suggesting that *no* warning would have kept the medical technician who administered the drug from making her terrible mistake, to

¹⁰⁸ *Id.* at 1203.

¹⁰⁹ See *supra* note 93; cf. *supra* text accompanying note 96.

¹¹⁰ *Wyeth*, 129 S.Ct. at 1217 (Alito, J., dissenting).

which she had sorrowfully confessed in settling a claim against her. In effect, the permission given the jury to find an inadequate warning looked like permission to reach into Wyeth's deep pocket, more than a genuine finding of any culpable failure on its part. If the FDA permitted Wyeth to keep the drug on the market for intravenous administration, with the approved and quite explicit warnings it in fact gave, was it not important to protect it against such outcomes? Much of Justice Alito's opinion is given over to a detailed review of the medical facts, the extensive dealings between Wyeth and the FDA about warnings, and the implications for other drugs that are extremely hazardous (but FDA-permitted) to be delivered intravenously if the juries of 50 states are permitted to find FDA-approved warnings inadequate.

In relation to *Geier*, Justice Alito's argument in *Wyeth* was, again and again, that the majority opinion required "turning yesterday's dissent into today's majority opinion.

"First, the Court denies the existence of a federal-state conflict in this case because . . . Vermont did not 'mandate a particular' label as a 'replacement' for the one that the jury nullified, and because the State stopped short of altogether 'contraindicating IV-push administration.' But as we emphasized in *Geier* (over the dissent's assertions to the contrary), the degree of a State's intrusion upon federal law is irrelevant—the Supremacy Clause applies with equal force to a state tort law that merely countermands a federal safety determination and to a state law that altogether prohibits car manufacturers from selling cars without airbags. . . .

"Second, the Court today distinguishes *Geier* because the FDA articulated its pre-emptive intent 'without offering States or other interested parties notice or opportunity for comment.' But the *Geier* Court specifically rejected the argument (again made by the dissenters in that case) that conflict pre-emption is appropriate only where the agency expresses its pre-emptive intent through notice-and-comment rulemaking. . . ."

And on to "Third," Fourth" and "Finally" examples.¹¹¹ Justices Kennedy and Breyer, regularly in the middle of these cases and emphasizing their particulars, did not agree.

¹¹¹ *Id.* at 1227-29.

* * *

Is there an editorial here? Perhaps the place to focus is not on the relation between national and state programs, but on the related but independent question how common law issues are to be dealt with in an age of statutes and regulation. In today's world, law is principally made by legislatures and by agencies—those organs of government possessing not only the democratic legitimacy, but also the capacity for large-scale action and technical expertise needed to implement the modern welfare and regulatory state. But what room does that leave for judges and juries? Must legislatures and agencies, today's primary law-givers, accept that judicial lawmakers can act independently unless given explicit instructions to fall in line? Or are the latter under some obligation to take the initiative in conforming the developments they undertake to what they reasonably find in the law that the former have been developing?

Just weeks after *Wyeth*, the Supreme Court decided *Atlantic Sounding Co. v. Townsend*,¹¹² a case that presented such a question in a context that was both pre-emption-free and state-free, admiralty. A maritime worker who had been injured on board a tugboat sought “maintenance and cure,” a traditional admiralty remedy, from his employer, who denied it. The worker then sued, seeking, *inter alia*, punitive damages for his employer's refusal to honor his claim. Assume the employer was in the wrong; were punitive damages available? If the matter were to be decided just on the basis of judicial precedent, the answer was clear: maritime law had recognized punitive damages as a proper element of relief when warranted by outrageous conduct.

Justice Thomas, writing for himself and the Court's more liberal Justices, so found after an extensive review of the common law and maritime law history. He had also to consider an

¹¹² 129 S.Ct.2561 (2009).

obstacle to his conclusion that the Court’s four other more conservative Justices—including Justice Kennedy, who had joined *Wyeth*—found persuasive. In *Miles v. Apex Marine Corp.*¹¹³ the Court had recognized a cause of action for wrongful death in “unseaworthiness” cases. In doing so, it had drawn on the provisions of the Jones Act¹¹⁴ (which extends to maritime workers the liberalizing measures for negligence actions that the earlier Federal Employees Liability Act¹¹⁵ had made available to railroad workers), the Death on the High Seas Act,¹¹⁶ and the uniform state practice of authorizing wrongful death actions by legislation. Unseaworthiness is the product of judge-made law, an admiralty tort distinct from either of those federal statutes (as well as state law). In drawing on those statutes, the *Miles* Court had imported their limitation to *actual* damages; punitive damages, it held, were not available. For Justice Thomas and his majority, it did not now follow that the action for maintenance and cure was similarly restricted; they reasoned that the restrictive element of the harmonization effected in *Miles* was not directed at the different remedy of maintenance and cure, but rather reflected appropriate limits for judicial activism when drawing on statutes to create new law. “The Court thus concluded that Congress’ judgment must control the availability of remedies for wrongful-death actions brought under general maritime law.”¹¹⁷ The cause of action for maritime and cure had long been established as a judge-made remedy for sailors, and the majority found no indication of a congressional purpose to restrict it. “Because punitive damages have long been an accepted remedy under general

¹¹³ 498 U.S. 19 (1990).

¹¹⁴ 46 USC § 30104(a).

¹¹⁵ 45 USC § 51 ff.

¹¹⁶ 46 USC § 30301 ff.

¹¹⁷ 129 S.Ct. at 2572.

maritime law, and because nothing in the Jones Act altered this understanding, such damages for the willful and wanton disregard of the maintenance and cure obligation should remain available in the appropriate case as a matter of general maritime law.”¹¹⁸

Writing again for the dissenting Justices, as he had in *Wyeth*, Justice Alito, made this argument:

“In order to understand our decision in *Miles*, it is necessary to appreciate the nature of the authority that the *Miles* Court was exercising. The Constitution, by extending the judicial power of the United States to admiralty and maritime cases, impliedly empowered this Court to continue the development of maritime law ‘in the manner of a common law court.’ In *Miles*, this Court explained how that authority should be exercised in an era in which statutory law has become dominant. . . .

‘We no longer live in an era when seamen and their loved ones must look primarily to the courts as a source of substantive legal protection from injury and death; Congress and the States have legislated extensively in these areas. *In this era, an admiralty court should look primarily to these legislative enactments for policy guidance.*’”¹¹⁹

Unlike the majority, the dissenters were unable to find any clear indication in the pre-Jones Act cases that “punitive damages were awarded for the willful denial of maintenance of cure—in an era when seamen were often treated with shocking callousness.”¹²⁰ Hence, the dissenters argued that the Jones Act’s preclusion of punitive damages “constitutes a powerful argument in favor of the development of a similar rule under general maritime law.”¹²¹

While majority and dissent differed in how they performed their analysis (the majority “liberally” finding greater law-making power in admiralty law itself), there seems to have been little difference on the general proposition put in *Miles*. “In this era, an admiralty court should

¹¹⁸ *Id.* at 2575.

¹¹⁹ *Id.* at 2575-76 (Alito, J., dissenting) (quoting *Miles*, 429 U.S. at 27 (emphasis in *Atlantic Sounding Co.*)).

¹²⁰ *Id.* at 2578.

¹²¹ *Id.*

look primarily to these legislative enactments for policy guidance.” Common-law innovation should be subordinated to statutory and regulatory developments, when the latter’s outlines and expectations are reasonably clear. And with such a proposition in mind, it becomes hard to imagine why considerations of federalism require that state common law development be favored, when state legislative or administrative development has been legislatively restricted.

Seen in such a light, isn’t the difference between *Wyeth* and *Geier* reasonably clear? State tort actions for failures of design and warning in the drug context were commonplace by 1976, when Congress passed section 360k of the Medical Devices Act yet declined to pass a similar provision for the FDCA. The FDA had for years recognized and accepted the common law’s role. The Third Restatement, from this perspective, states a proposition about the relation between regulatory and judicial outcomes entirely “in synch” with congressional expectations. If the FDA might possess authority nonetheless to corner the field (to convert minimum standards for warning into exclusive ones commanding the common law), at the very least it could be obliged to do so by the public and participatory means that can give its actions the force of law. The common law does not change by such surprising and unreasoned pronouncements as the FDA had essayed in *Wyeth*; why should regulatory law be seen to do so? For Standard 208, section 1392(d) provides a much stronger congressional determination of the need for uniformity; it addresses the federalism question by hamstringing those state actors most often thought of in the law-making context. It is, after all, general *legislative* authority that the Constitution reserves to the states. Particularly if one has in mind both section 1397(k)’s initial title characterizing its work as “Continuation” and the state of the common law when Congress enacted it, it is strange to find in that section permission to state judges and juries to do what state legislatures and agencies could not. As the *Wood* majority reasoned, “had Congress [foreseen the development of

design defect common law] the same logic that dictated . . . section 1392(d) would inescapably have dictated [it] extend to this situation.”¹²² NHTSA’s purpose to authorize variety and the reasons for it were clear; no stealth departure from prior understandings can be found in that agency’s behavior.

The allocation of authority between Nation and State, on this view, has little to do with abstract theories of federalism. It is all about regularity, reasonable expectations, and how a modern legal system appropriately goes about its business, coordinating the work of legislatures, agencies, and judges.

¹²² See *supra* note 33.